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VETERINARY SERVICES MEMORANDUM NO. 580.4

TO: Veterinary Services Management Team (VSMT)
Directors, (VS)
Area Veterinarians in Charge, (VS)
Foreign Animal Disease Diagnosticians
Area Epidemiology Officers, (VS)
Area Emergency Coordinators, (VS)

FROM: John R. Clifford
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Veterinary Services

OCT 22 2008

SUBJECT: Procedures for the Investigation of Potential Foreign Animal
Disease/Emerging Disease Incidents (FAD/EDI)

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I. PURPOSE

The purpose of this memorandum is to provide VS policy and procedures for the investigation and communication of a potential FAD/EDI. The classification of investigations, designation of diagnostic sample priority, and reporting of laboratory results are clarified. Procedures for the use of the National Animal Health Laboratory Network (NAHLN) Laboratories in FAD/EDI investigations are added.

II. CANCELLATION

VS Memorandum No. 580.4, dated March 30, 2004, is hereby cancelled. This memorandum has been substantially revised and must be reviewed in its entirety.

III. GENERAL INSTRUCTIONS AND CONCEPT OF OPERATIONS

A. State – Federal – Industry – Tribal Communication and Cooperation

The coordinated State-Federal-Industry-Tribal response to a potential FAD/EDI requires close communication and cooperation among all stakeholders and jurisdictions.

The Area Veterinarian in Charge or designee (AVIC) and the State Animal Health Official or designee (SAHO) must closely communicate and cooperate on all aspects of an FAD/EDI investigation from initiation to completion.

All FAD/EDI investigations must be initiated by the AVIC and/or the SAHO. All FAD/EDI investigations must be assigned by the AVIC and/or the SAHO to a Foreign Animal Disease Diagnostician (FADD). The AVIC and/or the SAHO is responsible for initiating a timely investigation of all credible reported or suspected FAD/EDI, including assigning an FADD to complete a site visit or field investigation as a required part of the investigation.

The AVIC and/or the SAHO will assign an FAD/EDI Case Coordinator(s) to assist with investigation support, communications, and Emergency Management Response System (EMRS) data entry, as required by the location, scale, complexity, or urgency of the investigation.

The AVIC will ensure the EMRS Referral Control Number (see Attachment V) is assigned and transmitted to the FADD and the SAHO.

B. Definition of Foreign Animal Disease/Emerging Disease Incident (FAD/EDI)

An FAD is a terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories. An EDI is defined as any terrestrial animal, aquatic animal or zoonotic disease not yet known or characterized, or any known or characterized terrestrial animal or aquatic animal disease in the United States or its territories that changes or mutates in pathogenicity, communicability, or zoonotic

potential to become a threat to terrestrial animals, aquatic animals, or humans. FAD/EDI may involve livestock, poultry, other animals, or wildlife.

In the event of an FAD/EDI investigation involving wildlife, VS will work in close collaboration, communication, and coordination with State, Tribal and Federal wildlife agencies that have primary jurisdictional authority and subject matter expertise for wildlife.

C. VS Deputy Administrator Responsibility and Authority for FAD/EDI Diagnostic Case Definitions

The classification and designation of FAD/EDI diagnostic case definitions are the responsibility and authority of the VS Deputy Administrator. Examples of case definitions include “presumptive” and “confirmed” FAD/EDI cases.

D. Definition of a Foreign Animal Disease Diagnostician (FADD)

A FADD is a Federal or State employed veterinarian who has successfully completed specialized FAD diagnostician training at the National Veterinary Services Laboratories (NVSL) Foreign Animal Disease Diagnostic Laboratory (FADDL) facility at Plum Island, NY; as well as any other specialized training and continuing education as required and administered by VS.

All FAD/EDI investigations must be initiated by the AVIC and/or the SAHO and assigned to a Foreign Animal Disease Diagnostician (FADD).

The AVIC will maintain a current roster of the currently available and equipped State employed and Federal employed FADDs in the State or territory. The VS Eastern Region Director or designee (Region Director) and VS Western Region Director or designee (Region Director) will maintain the regional rosters of currently available and equipped FADDs. The Chief Science Officer, Associate Deputy Administrator (ADA) for Emergency Management and Diagnostics (EM&D), will maintain a national roster of currently available or active FADDs. In the event an FADD is not available to conduct the investigation, then the AVIC and/or SAHO will dispatch the most qualified person available. Incidents where an FADD is not available to conduct an investigation must be reported to the Region Director or designee and to the National Center for Animal Health (NCAHEM) Preparedness and Incident Coordination Staff (NCAHEM PIC).

E. Emergency Management Response System Database (EMRS) and FAD/EDI Investigation Communications

The EMRS “Routine FAD/EDI Reporting” is a web-enabled database that is the official USDA APHIS database to record all FAD/EDI investigations. The EMRS database provides the capability to generate automatic email notices to selected VS personnel when FAD/EDI investigations are initiated in EMRS. This capability enables VS Region

and NCAHEM to monitor potential national “clusters” of FAD/EDI investigations on a real-time basis.

The EMRS database is accessed through the internet (<http://emrs.aphis.usda.gov>) and permits approved State, VS, and NAHLN Laboratory personnel access to enter and view investigations from their State or territory. All entries are confidential. EMRS database access at the State or territory is controlled and maintained by approval of the AVIC and the SAHO.

The AVIC will designate an FAD/EDI EMRS case coordinator to perform or facilitate EMRS data entry and database maintenance, as necessary.

An EMRS Manual for Routine FAD/EDI Investigations can be downloaded, as well as blank investigation forms. There is a training investigation module for practice investigations and an online tutorial.

In addition, because of the rapid exchange of information required during FAD/EDI investigations, communications such as phone calls, conference calls, email, and fax must be used when required (in addition to the official EMRS database to record information).

Situation reports, spot reports, diagnostic updates, and regulatory assessments will be produced as required by the urgency or complexity of the investigation, or at intervals requested by the Regional Director or designee, the VS ADA for EM&D, and the VS Deputy Administrator.

F. National Veterinary Services Laboratories (NVSL)

The USDA, APHIS NVSL safeguards United States animal health and contributes to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal-health diagnostic system.

NVSL is the official reference laboratory for FAD/EDI diagnostic testing and study in the United States. The NVSL must perform or officially confirm the results of all diagnostic testing and studies related to FAD/EDI investigations in the United States.

NVSL has two locations for FAD/EDI diagnostic testing: Ames, Iowa (NVSL-AMES) and Plum Island, New York (NVSL-FADDL).

Additional information regarding NVSL can be found at the following website: http://www.aphis.usda.gov/animal_health/lab_info_services/about_nvsl.shtml

G. National Animal Health Laboratory Network (NAHLN)

The NAHLN, created in 2002, is a comprehensive, coordinated, and modernized network of federal and state animal health laboratories and public agricultural institutions that address emergency biological and chemical threats to animal agriculture and the security of the food supply.

The NAHLN coordinates and networks Federal laboratory capacity with the extensive infrastructure (facilities, professional expertise, and support) and surge capacity of State supported laboratories. The purpose of the NAHLN is to enhance early detection of FAD agents and newly emerging diseases and to better respond to animal health emergencies (including bioterrorist events) that threaten the Nation's food supply and public health.

A current roster of the NAHLN laboratories and the testing that they are approved to perform can be found at the following website:

http://www.aphis.usda.gov/animal_health/nahln/labs.shtml

H. FAD/EDI Investigation Period Objectives and Critical Elements

1. The FAD/EDI investigation period is defined as the time from when the investigation is initiated until the time an FAD/EDI is ruled out or confirmed by FADD field investigation, official NVSL laboratory diagnostic testing or study results, or by official VS case definitions.
2. The objectives of an FAD/EDI investigation are to:
 - a. Provide a veterinary medical assessment that consists of:
 - i. Differential diagnosis;
 - ii. Classification of investigation, which is necessary to rank and prioritize the differential diagnosis in terms of the magnitude of suspicion for a foreign animal disease, in relation to the magnitude of suspicion for an endemic disease or condition (see Section IV);
 - iii. Designation of diagnostic sample priority, which is necessary to rank and prioritize the speed at which diagnostic samples are to be collected, transported, and tested. This ranking and priority includes both the magnitude of suspicion for a foreign animal disease, as well as the investigation location and consequences related to the speed of the investigation (see Section IV).
 - iv. The FADD, AVIC, and SAHO must concur on the classification of investigation and designation of diagnostic sample priority.
 - b. Provide presumptive and definitive diagnostic testing results as rapidly as required by the classification of investigation and designation of diagnostic sample priority, in order to rule out or confirm a suspected FAD/EDI agent.
 - c. Ensure that the appropriate veterinary medical countermeasures, regulatory actions, and communications are recommended and implemented during the investigation period, as necessary, to prevent and/or mitigate the dissemination of an FAD/EDI agent by interstate or international commerce of animals, animal products, meat, articles, or conveyances. Examples of interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; interstate or international import-export facilities.

The appropriate veterinary medical countermeasures, regulatory actions, and communications recommended and implemented during the investigation period will depend upon the classification of investigation and factors such as:

- i. The epidemiology of the suspected FAD/EDI agent (such as a highly contagious disease);
 - ii. The clinical and epidemiological findings obtained during the investigation as they correspond to the case definition for the suspected FAD/EDI disease agent (prior to obtaining presumptive or definitive diagnostic testing results);
 - iii. The State, Federal, territory, and Tribal jurisdictions and authorities apply to the specific situation.
3. Critical elements of an investigation include but are not limited to interviewing persons for incident history; observing clinical signs; performing physical examination of animals; collecting and analyzing epidemiological information; collecting diagnostic samples as necessary; performing necropsy studies as necessary; investigating trace backs and trace forwards of animals, animal products, meat, articles or conveyances as necessary; recommending and establishing intrastate quarantine as necessary (the authority of the SAHO); recommending and establishing interstate quarantines during the investigation period as necessary (the authority of the Secretary of Agriculture).
 4. Critical data and information collected during an investigation includes but is not limited to species affected, clinical signs, lesions observed, herd/flock morbidity and mortality rates, duration of illness, vaccination history, nutritional status, premises conditions, movement history, contact history, evidence or indication of pest or vector, and evidence or indication of zoonotic disease.

I. FAD/EDI Diagnostic Sample Testing and Studies – Capabilities and Options

NVSL is the official reference laboratory for FAD/EDI diagnostic testing and study in the United States. The NVSL must perform or officially confirm the results of all diagnostic testing and studies related to FAD/EDI investigations in the United States.

NVSL has two locations for FAD/EDI diagnostic testing: Ames, Iowa (NVSL-AMES) and Plum Island, New York (NVSL-FADDL). The routing of FAD/EDI diagnostic samples to NVSL-AMES or NVSL-FADDL by species or suspected disease is found in Attachment III.

The FADD, as part of the required site visit or field investigation, will determine if diagnostic sample testing or studies are necessary to rule out or confirm an FAD/EDI. The AVIC and SAHO retain the right to order diagnostic sample collection during an FAD/EDI investigation.

There are several capabilities and options available for FAD/EDI diagnostic testing depending upon the classification of FAD/EDI investigation and designation of

diagnostic sample priority (see Section III-H and Section IV). The diagnostic capabilities and options are the following:

1. For some FAD/EDI investigations, the extraordinary rapid transportation of diagnostic samples to NVSL-AMES or NVSL-FADDL by complete commercial carrier service will be the best option (such as Air Net, FedEx® Custom Critical, and UPS Express Critical).
2. For some FAD/EDI investigations, obtaining two sets of diagnostic samples will be the best option.
 - a. The first set of diagnostic samples must always be sent to the appropriate NVSL Laboratory (NVSL-AMES or NVSL-FADDL). The FADD, AVIC, and SAHO must concur with the classification of investigation and Priority 1, 2, 3 or A diagnostic sample designation (see Section IV).
 - b. The second set of diagnostic samples (if possible) will be sent to a NAHLN Laboratory to provide preliminary FAD/EDI diagnostic information prior to the receipt of diagnostic samples by the NVSL Laboratory.
 - c. If a second set of diagnostic samples can not be collected, then the samples that can be collected must be sent to the appropriate NVSL Laboratory, and not the NAHLN Laboratory.
 - d. Diagnostic samples must always be shipped or transported to the appropriate NVSL-AMES, NVSL-FADDL, or NAHLN Laboratory with a classification of investigation and designation of diagnostic sample priority concurrence by the FADD, AVIC, and SAHO.
 - e. The appropriate NVSL-AMES, NVSL-FADDL, or NAHLN Laboratory must be contacted by phone prior to the shipment or transport of any diagnostic samples, regardless of the priority designation.
 - f. In the event of an FAD/EDI disease outbreak situation, further guidance will be provided on diagnostic sample submissions to a NAHLN Laboratory.
3. For some FAD/EDI investigations, the rapid transportation of one set of diagnostic samples to NVSL-AMES or NVSL-FADDL will be the best option (such as FedEx® priority overnight).
4. In the event of an emergency situation when the appropriate NVSL Laboratory can not perform FAD/EDI diagnostic testing, depending upon the testing being performed, one set of diagnostic samples may be sent to the other NVSL Laboratory, and a second set of samples may be obtained for testing at a NAHLN Laboratory, or sent to another international reference laboratory.
5. The objectives for veterinary medical assessment, classification of investigation, and designation of diagnostic priority are covered in Section III-H. The protocol for classification of FAD/EDI investigations and correlation to designation of diagnostic sample priority is covered in Section IV.
6. Regardless of the diagnostic testing option employed, NVSL remains the official

confirmation laboratory for FAD/EDI testing in the United States.

J. Packaging and Labeling Requirements of Biological Substances for Shipment

1. The packaging and labeling of biological substances for shipment requires familiarity and training with current rules and regulations, which frequently change. Shippers are responsible for proper packaging, marking, labeling, documentation, classification, and identification of each shipment. **Failure to follow regulations can result in substantial financial penalties.**
 - a. [Title 9 Code of Federal Regulations \(CFR\), Parts 121 and 122](#): These USDA regulations cover 1) the transfer of select agents/toxins and 2) the permits needed to ship organisms and vectors.
 - b. [Title 42 CFR Part 72](#): These Health and Human Services regulations define terms such as biological products, diagnostic specimens, and etiologic agents, and provide requirements for packaging and labeling these materials for transportation in interstate commerce.
 - c. [Title 49 CFR Part 173](#): These Department of Transportation regulations contain general requirements for shipments and packaging. [49 CFR 173.134](#) defines infectious substances and related terms. [49 CFR 173.217](#) has additional requirements for shipments containing solid carbon dioxide (dry ice).
2. Additional Information can be found at the following website address:
http://www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml
3. Airline shipments also must be in compliance with current [International Air Transport Association \(IATA\) regulations](#) (www.iata.org) for dangerous goods.

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K. Table III-1: List of Terrestrial FAD Threats to the United States and its Territories. This List Does Not Contain All Potential Terrestrial FAD Threats.						
Foreign Animal Disease	Primary Type of Animal Affected	NVS Most Dangerous Disease List	Highly Contagious Disease (HCD)	Contagious Disease (CD)	Vector Borne Disease	Zoonotic Disease Potential
Highly Pathogenic Avian Influenza (HPNAI)	Avian, and Others	No. 1	Yes	Yes	No	Yes
Foot-and-Mouth Disease	All Cloven Hoofed Animals	No. 2	Yes	Yes	No	No
Rift Valley Fever	Bovine, Ovine, Caprine, Canine	No. 3	No	Yes	Yes	Yes
Exotic Newcastle Disease (Virulent ND)	Avian	No. 4	Yes	Yes	No	Yes Minor
Nipah Hendra	Swine, Equine	No. 5	Yes (Nipah)	Yes	No	Yes
Classical Swine Fever	Swine	No. 6	Yes	Yes	No	No
African Swine Fever	Swine	No. 7	Yes	Yes	Yes	No
Rinderpest	Bovine, Cloven Hoofed Animals	No. 9	Yes	Yes	No	No
Japanese Encephalitis	Equine, Swine	No. 10	No	No	Yes	Yes
African Horse Sickness	Equine, Donkey, Mules	No. 11	No	No	Yes	No
Venezuelan Equine Encephalitis	Equine, Avian,	No. 12	No	No	Yes	Yes
Contagious Bovine Pleuropneumonia	Bovine	No. 13	Yes	Yes	No	No
Heartwater (<i>Ehrlichia ruminantium</i>)	Bovine, Ovine, Caprine, others	No. 14	No	No	Yes	No
Akabane	Bovine, Ovine, Caprine	No. 17	No	No	Yes	No
Swine Vesicular Disease	Swine	n/a	Yes	Yes	No	No
Lumpy Skin Disease	Bovine	n/a	No	Yes	Yes	No
Peste des Petits Ruminants	Caprine, Ovine	n/a	Yes	Yes	No	No
Sheep Pox, Goat Pox	Ovine, Caprine	n/a	Yes	Yes	No	No
Glanders	Equine, Donkey, Mules	n/a	Yes	Yes	No	Yes
Dourine	Equine	n/a	No	Yes	No	No
Contagious Equine Metritis	Equine	n/a	No	Yes	No	No
Contagious Caprine Pleuropneumonia	Caprine	n/a	Yes	Yes	No	No
Nairobi Sheep Disease	Ovine, Caprine	n/a	No	No	Yes	Yes Minor
Surra (<i>Trypanosoma evansi</i>)	Equine, Donkey, Bovine, Others	n/a	No	Yes	Yes	No
Theileriosis (East Coast Fever)	Bovine	n/a	No	No	Yes	No
Bovine Babesiosis (FAD if detected outside of quarantine areas)	Bovine	n/a	No	No	Yes	No
Vesicular Stomatitis Virus	Equine, Bovine, Swine Sheep, Goats	n/a	No	Yes	Yes	Yes Rare
Equine Piroplasmiasis	Equine	n/a	No	No	Yes	No
Rabbit Hemorrhagic Disease	Domestic Rabbits (European Breeds)	n/a	Yes	Yes	No	No

NVS = National Veterinary Stockpile; Highly Contagious Disease = infectious disease transmitted rapidly or readily by direct or indirect contact; Contagious Disease = infectious disease transmitted by direct or indirect contact; Vector Borne Disease = disease transmitted by insect or arthropod; HPNAI = Highly Pathogenic Notifiable Avian Influenza.

L. Table III-2: List of Foreign Pest Threats to the United States and its Territories. This List Does Not Contain All Potential Foreign Pest Threats.				
Foreign Pest Common Name	Foreign Pest Scientific Name	Primary Type of Animal Affected	Disease Transmitted; Condition Caused	Zoonotic Disease Potential
Screwworm - New World	<i>Cochliomyia hominivorax</i>	Warmblood Animals	Myiasis	Myiasis
Screwworm – Old World	<i>Chrysomya bezziana</i>	Warmblood Animals	Myiasis	Myiasis
Bont Tick	<i>Amblyomma hebraeum</i>	Bovine, Reptiles, Other Species	Heartwater	Tick Typhus
Tropical Bont Tick	<i>Amblyomma variegatum</i>	Bovine, Reptiles, Other Species	Heartwater, Nairobi Sheep Disease, CCHF	Tick Typhus CCHF Yellow Fever
Brown Ear Tick	<i>Rhipicephalus appendiculatus</i>	Bovine, Ovine, Caprine, Other Species	Heartwater, East Coast Fever, Nairobi Sheep Disease	Tick Typhus
European Castor Bean Tick	<i>Ixodes ricinus</i>	Bovine, Ovine, Caprine, Other Species	Bovine Babesiosis	CCHF Lyme Disease
Southern Cattle Tick	<i>Rhipicephalus microplus</i> (formerly <i>Boophilus microplus</i>)	Bovine, Ovine, Caprine, Other Species	Bovine Babesiosis Anaplasmosis	Susceptible Human Population - Splenectomized
Cattle Fever Tick	<i>Rhipicephalus annulatus</i> (formerly <i>Boophilus annulatus</i>)	Bovine, Ovine, Caprine, Other Species	Bovine Babesiosis Anaplasmosis	Susceptible Human Population - Splenectomized
Sheep Scab Sheep Mange	<i>Psoroptes ovis</i>	Bovine, Ovine, Other Species	Mange	No
Licking Fly	<i>Musca vitripennis</i>	Bovine	Bovine Filariosis	No
Louse Fly	<i>Hippobosca longipennis</i>	Canine, Livestock, Other Species	Bite Only	Bite Only

Myiasis = fly larvae feeding on the host living tissue; Mange = hair loss, itching and inflammation from mite infestation;
Tick Typhus = *Rickettsia conorii* (human disease); CCHF = Crimean Congo Hemorrhagic Fever.

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IV. CLASSIFICATION OF FAD/EDI INVESTIGATIONS AND CORRELATION TO DESIGNATION OF DIAGNOSTIC SAMPLE PRIORITY 1, 2, 3, OR A

A. Classification of FAD/EDI Investigations and Correlation to Designation of Diagnostic Sample Priority 1, 2, 3, or A: Defined in Three Tables

Table IV-1: Classification of FAD/EDI Investigations and Correlation to Diagnostic Sample Priority 1, 2, 3, or A

Table IV-2: Classification of FAD/EDI Investigations and Definitions

Table IV-3: Designation of Diagnostic Sample Priority 1, 2, 3, or A and Correlation to Speed of Diagnostic Sample Collection, Transport, and Diagnostic Study

Table IV-1: Classification of FAD/EDI Investigations and Correlation to Designation of Diagnostic Sample Priority 1, 2, 3, or A		
Classification of Investigations	Designation of Diagnostic Sample Priority	
High Suspicion of an FAD/EDI <i>Formerly “Highly Likely”</i>	Diagnostic Sample Priority 1	
Intermediate Suspicion of an FAD/EDI <i>Formerly “Possible”</i>	Diagnostic Sample Priority 2 or Priority A	
Low Suspicion of an FAD/EDI <i>Formerly “Unlikely”</i>	Diagnostic Sample Priority 3 or Priority A	

Table IV-2: Classification of FAD/EDI Investigations and Definitions	
Classification of Investigations	Definition
High Suspicion of an FAD/EDI <i>Formerly “Highly Likely”</i>	The findings of the investigation conducted by the FADD are consistent with an FAD/EDI and are generally inconsistent with an endemic disease/condition, or are discordant with an endemic disease/condition. The veterinary medical and regulatory assessments are consistent with a <u>high suspicion of an FAD/EDI classification</u> (<i>formerly “Highly Likely” classification</i>).
Intermediate Suspicion of an FAD/EDI <i>Formerly “Possible”</i>	The findings of the investigation conducted by the FADD are consistent with an FAD/EDI but are also consistent with an endemic disease/condition. The veterinary medical and regulatory assessments are consistent with an <u>intermediate suspicion of an FAD/EDI classification</u> (<i>formerly “Possible” classification</i>).
Low Suspicion of an FAD/EDI <i>Formerly “Unlikely”</i>	The findings of the investigation conducted by the FADD are generally inconsistent with an FAD/EDI and are consistent with an endemic disease/condition. The veterinary medical and regulatory assessments are consistent with a <u>low suspicion of an FAD/EDI classification</u> (<i>formerly “Unlikely” classification</i>).

Table IV-3: Designation of Diagnostic Sample Priority 1, 2, 3, or A and Correlation to Speed of Sample Collection, Transportation, and Diagnostic Study	
Priority	Speed of Sample Collection, Transportation, and Diagnostic Study
Priority 1	<ul style="list-style-type: none"> ▪ The Priority 1 designation is <u>ONLY</u> used for the <u>High Suspicion of an FAD/EDI classification</u>. ▪ Rapid to extraordinary rapid methods must be used to collect, transport, and study diagnostic samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies as rapidly as possible upon sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by state. ▪ Extraordinary rapid collection and transportation methods will be required when the Priority 1 investigation includes a highly contagious FAD/EDI in the differential diagnosis; or when the Priority 1 investigation includes animals, animal products, meat, articles or conveyances involved or engaged in interstate or international commerce.¹ ▪ Rapid transportation methods include express shipping services such as FedEx® priority overnight. ▪ Extraordinary rapid transportation methods include the use of hand carried samples, couriers, counter-to-counter services, and complete commercial services such as Air Net, FedEx® Custom Critical, and UPS Express Critical.
Priority 2	<ul style="list-style-type: none"> ▪ The Priority 2 designation is used for the <u>Intermediate Suspicion of an FAD/EDI classification</u>. ▪ Rapid methods must be used to collect, transport, and study diagnostic samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies immediately if the samples arrive at the laboratory before the close of the work day. NVSL will use overtime to complete testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by state. Diagnostic samples arriving after the close of the work day will be examined first thing the following day. Diagnostic samples received Saturday will be tested or studied on Saturday only with prior notification and discussion with NVSL and NAHLN laboratory personnel. ▪ Rapid transportation methods include express shipping services such as FedEx® priority overnight.
<p>¹ Examples of animals, animal products, meat, articles, or conveyances in interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; interstate or international import-export facilities.</p>	
<p>Table IV-3 is continued on the next page.</p>	

Table IV-3: Designation of Diagnostic Sample Priority 1, 2, 3, or A and Correlation to Speed of Sample Collection, Transportation, and Diagnostic Study, Continued	
Priority	Speed of Sample Collection, Transportation, and Diagnostic Study
Priority 3	<ul style="list-style-type: none"> ▪ The Priority 3 designation is only used for the <u>Low Suspicion of an FAD/EDI classification</u>. ▪ Routine methods will be used to collect, transport, and study diagnostics samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies in accession order as received. NVSL and NAHLN overtime services will not be used for Priority 3 investigations. The Priority 3 designation is also used for routine surveillance samples. ▪ Routine transportation methods include express shipping services such as FedEx® priority overnight (to ensure preservation of diagnostic sample quality).
Priority A	<ul style="list-style-type: none"> ▪ The Priority A designation is ONLY used for <u>Intermediate Suspicion of an FAD/EDI classification</u> or <u>Low Suspicion of an FAD/EDI classification</u> when animals, animal products, meat, articles or conveyances in interstate, or international commerce are involved and/or potentially held, delayed or quarantined pending the results of diagnostic testing or studies for an FAD; or when other known or potential circumstances associated with the investigation indicate that it is prudent to obtain diagnostic sample testing results as rapidly as possible.¹ ▪ Rapid to extraordinary rapid measures must be employed to collect, transport, and study diagnostic samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies as rapidly as possible upon sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by state. ▪ Rapid transportation methods include express shipping services such as FedEx® priority overnight. ▪ Extraordinary rapid transportation methods include the use of hand carried samples, couriers, counter-to-counter services, and complete commercial services such as Air Net, FedEx® Custom Critical, and UPS Express Critical.
<p>¹ Examples of animals, animal products, meat, articles, or conveyances in interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; interstate or international import-export facilities.</p>	
<p>This is the continuation of Table IV-3</p>	

B. General Instructions for the Classification of FAD/EDI Investigations and Designation of Diagnostic Sample Priority 1, 2, 3, or A

The AVIC or designee and the SAHO or designee must closely communicate and cooperate on all aspects of an FAD/EDI investigation from initiation to completion.

1. The FADD, AVIC, and SAHO must concur on the:
 - a. Classification of investigation, and;
 - b. Designation of diagnostic sample priority 1, 2, 3, or A.
2. The Priority 1 diagnostic sample designation is **ONLY** used for the High Suspicion of an FAD/EDI classification.
3. The Priority A diagnostic sample designation is **ONLY** used for:
 - a. The Intermediate Suspicion of an FAD/EDI classification; or,
 - b. The Low Suspicion of an FAD/EDI classification; or,
 - c. When animals, animal products, meat, articles, or conveyances in interstate or international commerce are involved and/or potentially held, delayed or quarantined pending the results of diagnostic testing or studies for an FAD/EDI; examples of animals, animal products, meat, articles, or conveyances in interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; interstate, or international import-export facilities;
 - d. Or when other known or potential circumstances associated with the investigation indicate that it is prudent to obtain diagnostic sample testing results as rapidly as possible, regardless of the likelihood of the presence of an FAD/EDI.
4. If there are questions, concerns, or disagreement regarding the classification of an investigation or the designation of diagnostic sample Priority 1, 2, 3, or A by the FADD, AVIC, and the SAHO, then there must be an immediate conference call of the FADD, AVIC, and SAHOs with the Region Director or designee, NVSL Director, and NCAHEM PIC. NCAHEM PIC and Region Director or designee will provide the capability to host and coordinate conference calls.
5. The AVIC and SAHO will determine a diagnostic sample submission plan with the FADD, NVSL, and the NAHLN Laboratory Director. If the preliminary decision is made to submit a second set of diagnostic samples to the NAHLN laboratory, then the AVIC and/or SAHO must instruct the FADD to follow the procedures for submitting a second set of diagnostic samples to the NAHLN laboratory. The AVIC, FADD, and/or SAHO will notify the NAHLN Laboratory Director if there is a change in the NAHLN laboratory submission plan after the FADD performs the investigation.
6. The appropriate NVSL-AMES or NVSL-FADDL laboratory must be contacted by the AVIC, SAHO, or FADD by phone prior to the shipment or delivery of all diagnostic samples, regardless of the Priority 1, 2, 3, or A diagnostic sample designation. If a

second set of samples is going to be submitted to a NAHLN Laboratory, then the NAHLN Laboratory must be contacted by phone prior to the transportation or shipment of any diagnostic samples.

7. EMRS must be used for all FAD/EDI investigations. Automatic email notifications are generated for all FAD/EDI investigations. Telephone notification to NCAHEM PIC is NOT required for Intermediate Suspicion of an FAD/EDI classification, Low Suspicion of an FAD/EDI classification, or Priority 2, or Priority 3 diagnostic sample designations.
8. The AVIC or FADD must IMMEDIATELY contact NCAHEM PIC and Region Director or designee by phone and prior to the shipment or transport of diagnostic samples when:
 - a. High Suspicion of an FAD/EDI classification is assigned; or,
 - b. Priority 1 diagnostic sample designation is assigned; or,
 - c. Priority A diagnostic sample designation is assigned.

These diagnostic samples will require rapid to extraordinary rapid transportation methods to include courier, counter-to-counter service, and complete commercial carrier services such as FedEx® Custom Critical, AirNet, or UPS Express Critical.

9. Following initial telephone notifications of a High Suspicion of an FAD/EDI Classification, or Priority 1 diagnostic sample designation, or any Priority A diagnostic sample designation, the FADD, AVIC, SAHOs, Region Director(s) or designee(s), NVSL Director, and NCAHEM PIC will immediately discuss by conference calls, within 2 hours of NCAHEM PIC notification:
 - a. The rapid to extraordinary rapid methods used to collect, transport, and test diagnostic samples;
 - b. The appropriate veterinary medical countermeasures, regulatory actions, and communications recommended and implemented during the investigation period, as necessary, to prevent and/or mitigate the dissemination of an FAD/EDI agent by interstate or international commerce of animals, animal products, meat, articles, or conveyances.
 - c. The appropriate veterinary countermeasures, regulatory actions, and communications recommended and implemented during the investigation period will depend upon the classification of investigation and factors such as:
 - i. The epidemiology of the suspected FAD/EDI agent (such as a highly contagious disease);
 - ii. The clinical and epidemiological findings obtained during the investigation as they correspond to the case definition for the suspected FAD/EDI disease agent (prior to obtaining presumptive or definitive diagnostic testing results);
 - iii. The State, Federal, territory, and Tribal jurisdictions and authorities that apply to the specific situation.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X					
X	X					
X	X	X				
X	X					
X	X	X				
X			X			X

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS

The AVIC or designee and the SAHO or designee must closely communicate and cooperate on all aspects of an FAD/EDI investigation from initiation to completion.

A. Procedures for Initiating and Conducting an FAD/EDI Investigation

1. The AVIC and/or SAHO will determine if the report is credible and constitutes an FAD/EDI threat to associated livestock, poultry, or other animals, and warrants an investigation or not.
2. The AVIC and/or SAHO will initiate a timely investigation of all credible reports or incidents by assigning the most readily available FADD to complete an investigation.
3. The AVIC will ensure the EMRS Referral Control Number (see Attachment V) is assigned and transmitted to the FADD and SAHO.
4. The AVIC and/or SAHO will assign FAD/EDI Case Coordinator(s) for communication, investigation support, and EMRS Data Entry as needed or required by the location, scale, complexity, or urgency of the investigation.
5. The AVIC, SAHO, and FADD will ensure that an investigation is initiated (FADD will contact the producer, owner, manager, veterinary practitioner, or veterinary diagnostic laboratory, etc., as required by details of the investigation) within 8 hours of assignment and ensure that the site visit or field investigation with examination is conducted within 24 hours of assignment.
6. However, credible reports of a potential FAD/EDI incident where animals, animal products, meat, articles, or conveyances are involved or engaged in interstate or international commerce must be investigated immediately. In such a situation, if an FADD is not immediately available, the AVIC must contact the Region Director or designee and NCAHEM PIC to determine an action plan for the rapid conduct of the FAD investigation.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X				
		X		X		
X	X	X				

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

A. Procedures for Initiating and Conducting an FAD/EDI Investigation (Continued)

7. The AVIC and/or SAHO will ensure that an initial case report is prepared and transmitted (email, fax, or phone as needed) to the FADD and counterpart. The report will include as much of the following information as possible:
 - a. The date and time of the initial report;
 - b. Contact information (phones, fax, and premises address) for producer, owner, manager, agent, veterinary practitioner, or veterinary diagnostic lab making the suspect report;
 - c. Primary clinical complaints and/or suspected disease agent; species affected; number of species and animals on premises; number of species and animals affected, duration of the illness; concentration point or distribution center where animals, animal products, meat, articles, or conveyances may be involved or engaged in interstate or international commerce;
 - d. The initial EMRS Herd Exam Form and Investigation Summary Form.

8. The FADD will contact the appropriate NVSL-AMES or NVSL-FADDL laboratory personnel and employ their expertise to ensure the correct collection, preparation, and handling for any diagnostic samples collected during the investigation.

9. The FADD, AVIC and/or SAHO will ensure that a classification of investigation and designation for diagnostic sample Priority 1, 2, 3, or A is assigned when the FADD is conducting or has completed the initial investigation. The FADD, AVIC, and SAHO must concur on the classification of investigation and designation of diagnostic sample Priority 1, 2, 3, or A.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X	X	X	X	X
		X	X	X		
		X	X	X		
X	X	X				
X	X	X				

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

A. Procedures for Initiating and Conducting an FAD/EDI Investigation (Continued)

10. If there are any questions, concerns or disagreement at the Area, State, or territory regarding the classification of an investigation or the designation of diagnostic sample priority 1, 2, 3, or A, then there must be an immediate conference call of the FADD, AVIC, and SAHOs with Region Director or designee, NCAHEM PIC, NVSL Director and NAHLN Laboratory Director. NCAHEM and/or VS Region will provide the capability to host conference calls.
11. The FADD must contact the appropriate NVSL-AMES, NVSL-FADDL and/or NAHLN Laboratory by phone prior to shipping or transport of diagnostic samples regardless of Priority 1, 2, 3, or A diagnostic sample designation. Information required:
 - a. Airbill tracking number, or other transport identification;
 - b. Estimated time of arrival;
 - c. Classification of investigation, Priority 1, 2, 3, or A diagnostic sample designation.
12. The FADD will ensure that a VS Form 10-4 Specimen Submission Form is completed for all diagnostic samples submitted to NVSL-AMES, NVSL-FADDL and/or NAHLN Laboratory. The completed VS Form 10-4 must contain as much of the requested information as possible, for custody and control purposes, and to assist the laboratory diagnostician (see Attachment III, 1-9).
13. The FADD will contact the SAHO, AVIC, and Tribal official with a recommendation or decision to establish an intrastate quarantine during the investigation period (authority of the SAHO).
14. The AVIC and FADD will ensure EMRS data entry and follow-up forms are completed in a timely manner:
 - a. Ensure the EMRS FAD/EDI Herd Exam Form, Lab Submission Form, Investigation Summary Report is completed in a timely manner.
 - b. Email or transmit the EMRS FAD/EDI Investigation Summary report to the AVIC and SAHO when data entry is completed.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X			X			X
X	X	X	X	X	X	X
X	X	X	X	X	X	X

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

B. Procedures for Notifications During an FAD/EDI Investigation

1. The AVIC or FADD will IMMEDIATELY contact NCAHEM PIC and Region Director or designee by phone, and prior to shipment or transport of diagnostic samples, when:
 - a. High Suspicion of an FAD/EDI classification is assigned; or,
 - b. Priority 1 diagnostic sample designation is assigned; or,
 - c. Priority A diagnostic sample designation is assigned.

These diagnostic samples will require rapid to extraordinary rapid transportation methods to include courier, counter-to-counter services, and complete commercial services such as FedEx® Custom Critical, AirNet, or UPS Express Critical.

2. The AVIC, FADD, Region Director or Designee, NVSL Director, NAHLN Laboratory Director, NCAHEM PIC, SAHOs, and Tribal Officials will immediately discuss by phone or conference call, within 2 hours of NCAHEM notification, the rapid to extraordinary rapid measures used to collect and transport diagnostic samples for any High Suspicion of an FAD/EDI classifications, or for any Priority 1 or Priority A diagnostic sample designations. NCAHEM PIC and/or Region Director or designee will provide the capability to host conference calls.

3. For High Suspicion of an FAD/EDI classifications, or for any Priority 1 or Priority A diagnostic sample designations, the AVIC, FADD, VS Region, NVSL, NAHLN, NCAHEM, SAHOs, and Tribal Officials will immediately discuss by phone or conference call, within 2 hours of NCAHEM notification, the appropriate communications, veterinary medical countermeasures, and regulatory actions recommended and implemented during the investigation period, as necessary, to prevent and/or mitigate the dissemination of an FAD/EDI agent by interstate or international commerce of animals, animal products, meat, articles or conveyances. NCAHEM PIC and/or Region Director or designee will provide the capability to host conference calls.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X	X	X	X	X
						X
			X			X
X	X	X	X	X	X	X
X	X		X			X

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

B. Procedures for Notifications During an FAD/EDI Investigation (Continued)

4. The AVIC, FADD, Region Director or designee, NVSL Director, and NCAHEM PIC, VS ADAs and VS Deputy Administrator are responsible for making any recommendations to establish interstate movement restrictions during the investigation period (authority of the Secretary of the Agriculture). This recommendation is conducted in close communication and cooperation with the SAHOs and NAHLN Laboratory Director.
5. NCAHEM PIC will immediately report to the VS Deputy Administrator, VS ADAs, APHIS Legislative and Public Affairs (LPA), and the USDA Homeland Security Office all reports of:
 - a. High Suspicion of FAD/EDI investigations;
 - b. Priority 1 diagnostic sample submissions.
 - c. Priority A diagnostic sample submissions.
6. NCAHEM PIC and Region Director or designee will immediately report to the VS Deputy Administrator and VS ADAs, any recommendations from the AVIC or SAHO to establish interstate movement restrictions during the investigation period (authority of the Secretary of the Agriculture).
7. In addition to using EMRS, the AVIC, FADD, Region Director or designee, NVSL Director, NAHLN Laboratory Director and NCAHEM PIC will provide written and verbal situation reports, operational updates, and diagnostic updates at intervals requested by the Region Director, the VS ADAs, and the VS Deputy Administrator. NCAHEM PIC and Region Director or designee will provide the capability to host conference calls as needed.
8. NCAHEM will activate the National Veterinary Stockpile (NVS) during the investigation period when requested by the Region Director or designee, VS ADAs, or the VS Deputy Administrator. This activation is conducted in close cooperation and communication with the AVIC, SAHOs, and Tribal Officials. *The NVS Planning Guide for Federal, State and Local Officials* outlines procedures for activating the NVS.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X	X	X		X
X				X		X
X	X	X	X			
X	X	X				

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

C. Procedures for the Reporting of Diagnostic Sample Testing Results

1. When NVSL is the only Laboratory performing diagnostic testing for an FAD/EDI investigation:

- a. **The NVSL Director or designee will immediately report all *positive or suspect* laboratory findings by phone to the VS Deputy Administrator and VS ADA for EM&D. After this initial notification the NVSL director or designee will immediately notify the AVIC.** NCAHEM PIC will coordinate conference calls with the VS Deputy Administrator, VS Regional Director(s), VS ADAs, VS Emergency Management Leadership Team (EMLT), AVIC(s), FADD, SAHO(s), NVSL Director, and LPA for response actions and communications. These conference calls must occur within 2 hours of the notification to NCAHEM PIC staff.
- b. The NVSL Director or designee will report all *negative or not detected* laboratory results to the AVIC and NCAHEM PIC, regardless of the assigned Priority 1, 2, 3, or A diagnostic sample designation in a timely manner.
- c. The AVIC will report all NVSL preliminary and final diagnostic testing results to the SAHO, Region Director or designee, FADD, and case coordinator, if assigned. The AVIC will immediately report all *positive or suspect* results, and negative results from Priority 1 or Priority A diagnostic sample submissions.
- d. The FADD, after consultation with the AVIC and SAHO, will notify the producer, owner, manager, agent, veterinarian, etc. of FAD/EDI diagnostic testing results in a timely manner.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
				X	X	
X	X	X	X	X	X	X
	X			X	X	
X				X		X

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

C. Procedures for the Reporting of Diagnostic Sample Testing Results (Continued)

2. When NVSL and a NAHLN Laboratory are both performing diagnostic testing for an FAD/EDI investigation:
 - a. **The NAHLN Laboratory Director or designee will immediately report all *positive, suspect, negative, not detected, or inconclusive* NAHLN diagnostic findings, whether preliminary or final, to the NVSL Director or designee for notification and consultation.**
 - b. **Unless there are already existing NVSL diagnostic results that are *negative or not detected*, the NVSL Director or designee will immediately report all *positive, suspect, or inconclusive* NAHLN diagnostic results, whether preliminary or final, to the VS Deputy Administrator and VS ADA for EM&D. After this initial notification, the NVSL Director or designee will immediately notify the AVIC of the NAHLN State and the AVIC of the submitting State (if different). NCAHEM will coordinate conference calls with the VS Deputy Administrator, VS Regional Director(s), VS ADAs, VS EMLT, AVIC(s), FADD, SAHO(s), NVSL Director, NAHLN Laboratory Director, and LPA for response actions and communications. These conference calls must occur within 2 hours of the notification to NCAHEM staff.**
 - c. After the notification and consultation with the NVSL director or designee, the NAHLN Laboratory Director or designee will immediately notify their SAHO of all laboratory results.
 - d. The NVSL Director or designee will report all *negative or not detected* NAHLN diagnostic results to the AVIC of the NAHLN State and to the AVIC of the submitting State (if different), and to the NCAHEM PIC, regardless of the assigned Priority 1, 2, 3, or A diagnostic sample designation.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X	X			
X	X	X				
X	X	X	X	X	X	X
X				X		X

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

C. Procedures for the Reporting of Diagnostic Sample Testing Results (Continued)

2. When NVSL and a NAHLN Laboratory are both performing diagnostic testing for an FAD/EDI investigation (continued):
 - e. The AVIC of the submitting State will report all preliminary and final NAHLN diagnostic testing results to the SAHO, VS Region, and FADD of the submitting state. The AVIC will immediately report all *positive* or *suspect* results, and negative results from Priority 1 or Priority A diagnostic sample submissions.
 - f. The FADD, after consultation with the AVIC and SAHO, will notify the producer, owner, manager, agent, veterinarian, etc., of the NAHLN diagnostic testing results in a timely manner.
 - g. **The NVSL Director or designee will immediately report all *positive* or *suspect* NVSL diagnostic findings to the VS Deputy Administrator and VS ADA for EM&D. After this initial notification the NVSL director or designee will immediately notify the AVIC of the NAHLN State and the AVIC of the submitting State (if different). NCAHEM PIC will coordinate conference calls with the VS Deputy Administrator, VS Regional Director(s), VS ADAs, VS EMLT, AVIC(s), FADD, SAHO(s), NVSL Director, NAHLN Laboratory Director, and LPA for response actions and communications. These conference calls must occur within 2 hours of the notification to NCAHEM staff.**
 - h. The NVSL Director or designee will report all *negative* or *not detected* NVSL diagnostic results to the AVIC of the NAHLN State, the NAHLN Laboratory Director of the submitting State, and to the AVIC of the submitting State (if different), and to NCAHEM PIC, regardless of the assigned Priority 1, 2, 3 or A diagnostic sample designation.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X	X			
X	X	X				
				X	X	
				X	X	

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

C. Procedures for the Reporting of Diagnostic Sample Testing Results (Continued)

2. When NVSL and a NAHLN Laboratory are both performing diagnostic testing for an FAD/EDI investigation (continued):

i. The AVIC of the submitting State will report all preliminary and final NVSL diagnostic testing results to the SAHO, VS Region, FADD and case coordinator if assigned. The AVIC will immediately report all *positive* or *suspect* results, and immediately report all results from Priority 1 or Priority A diagnostic sample submissions.

j. The FADD, after consultation with the AVIC and SAHO, will notify the producer, owner, manager, agent, veterinarian, etc., of the NVSL diagnostic testing results in a timely manner.

k. Any NAHLN Laboratory performing FAD/EDI investigation diagnostic testing must follow established NAHLN Laboratory reporting guidelines and follow-up actions. Discordant results will be resolved between NVSL and the NAHLN Laboratory according to the discordant results plan.

3. In the event of an emergency situation when NVSL cannot perform FAD/EDI investigation diagnostic testing, and only a NAHLN Laboratory can perform diagnostic testing:

a. **The NAHLN Laboratory Director or designee will immediately report all *positive, suspect, negative, not detected, or inconclusive* NAHLN diagnostic findings, whether preliminary or final, to the NVSL Director or designee for notification and consultation.**

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X	X	X	X	X
	X			X	X	
X				X		X
X	X	X	X			

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

C. Procedures for the Reporting of Diagnostic Sample Testing Results (Continued)

3. In the event of an emergency situation when NVSL can not perform FAD/EDI investigation diagnostic testing, and only a NAHLN Laboratory can perform diagnostic testing (continued):

- b. **The NVSL Director or designee will immediately report all *positive, suspect, or inconclusive* NAHLN diagnostic laboratory results, whether preliminary or final, to the VS Deputy Administrator and the VS ADA for EM&D. After this initial notification, the NVSL Director or designee will immediately notify the AVIC of the NAHLN State and the AVIC of the submitting State (if different). NCAHEM will coordinate conference calls with the VS Deputy Administrator, VS Regional Director(s), VS ADAs, VS EMLT, AVIC(s), FADD, SAHO(s), NVSL, NAHLN Laboratory Director, and LPA for response actions and communications. These conference calls must occur within 2 hours of the notification to NCAHEM PIC staff.**
- c. After the notification and consultation with the NVSL Director or designee, the NAHLN Laboratory Director or designee will immediately notify their SAHO.
- d. The NVSL Director or designee will report all *negative or not detected* NAHLN diagnostic results to the AVIC of the NAHLN State and to the AVIC of the submitting State (if different), and to NCAHEM, regardless of the assigned Priority 1, 2, 3, or A diagnostic sample designation.
- e. The AVIC of the submitting State will report all preliminary and final NAHLN diagnostic testing results to the SAHO, Region Director or designee, FADD of the submitting state, and case coordinator if assigned. The AVIC will immediately report all *positive or suspect* results and negative results from Priority 1 or Priority A diagnostic sample submissions.

Parties Involved						
AVIC	SAHO	FADD	REGION Director	NVSL Director	NAHLN Director	NCAHEM PIC
X	X	X				
				X	X	
X	X	X				
X	X			X		
X			X			

V. SPECIFIC INSTRUCTIONS FOR FAD/EDI INVESTIGATIONS, CONTINUED

C. Procedures for the Reporting of Diagnostic Sample Testing Results (Continued)

3. In the event of an emergency situation when NVSL can not perform FAD/EDI investigation diagnostic testing, and only a NAHLN Laboratory can perform diagnostic testing (continued):
 - f. The FADD, after consultation with the AVIC and SAHO, will notify the producer, owner, manager, agent, veterinarian, etc., of the NAHLN diagnostic testing results in a timely manner.
 - g. Any NAHLN Laboratory performing FAD/EDI investigation diagnostic testing must follow established NAHLN Laboratory reporting guidelines and follow-up actions.

D. Procedures for the Closure of an FAD/EDI Investigation in EMRS

1. With approval of the AVIC, and notification to the SAHO, FAD/EDI investigations will be closed in EMRS by the FADD or EMRS case coordinator.
2. The AVIC and/or SAHO will ensure that electronic EMRS FAD/EDI Investigation Summary, Follow-up Forms, and attachment feature will be used to record all follow-up information, laboratory results, quarantine release dates, etc. NVSL will ensure final laboratory reports are forwarded to the Area Office.
3. The VS Region Director or designee will monitor FAD/EDI investigations in EMRS. Investigations open for longer than 30 days will be identified for follow-up action and case closure with the AVIC.

VI. AUTHORITY

A. The Animal Health Protection Act (AHPA), 7 U.S.C. 8301 et seq.

The Animal Health Protection Act (AHPA), 7 U.S.C. 8301 et seq. enables the Secretary of Agriculture to prevent, detect, control, and eradicate diseases and pests of animals in order to protect animal health, the health and welfare of people, economic interests of livestock and related industries, the environment, and interstate and foreign commerce in animals and other articles. The AHPA provides a broad range of authorities to use in the event of diseases and pests of animals in the United States, including FADs and emerging diseases, and to prevent the introduction of such diseases into the United States.

The Secretary of Agriculture is specifically authorized to carry out operations and measures to detect, control, or eradicate any pest or disease of livestock, which includes poultry, 7 U.S.C. 8308, and to promulgate regulations and issue orders to carry out the AHPA (see 7 U.S.C. 8315). The Secretary of Agriculture may also prohibit or restrict the importation, entry, or interstate movement of any animal, article, or means of conveyance to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. [7 U.S.C. 8303-8305]

Section 421 of the Homeland Security Act, 6 U.S.C. 231, transferred to the Secretary of Homeland Security certain agricultural import and entry inspection functions under the AHPA, including the authority to enforce the prohibitions or restrictions imposed by USDA.

The Secretary of Agriculture, under certain specified circumstances, may declare an extraordinary emergency to regulate intrastate activities or commerce. [7 U.S.C. 8306]

The Secretary of Agriculture also has authority to cooperate with other Federal agencies, States, or political subdivisions of States, national or local governments of foreign countries, domestic or international organizations or associations, Indian tribes, and other persons to prevent, detect, control, or eradicate diseases and pests of animals, including FADs and emerging diseases. [7 U.S.C. 8310]

B. Title 9 of the Code of Federal Regulations (CFR)

Title 9 of the Code of Federal Regulations (CFR) provides specific regulations for the control and eradication of diseases, including FADs. For example, animals or poultry affected with any of the following diseases, or any other communicable foreign disease not known to exist in the United States, shall not be moved interstate. Interstate is defined as from one State into or through any other State. [9 CFR 71.3 (b)]

African Swine Fever [9 CFR 53, 9 CFR 71]
Classical Swine Fever [9 CFR 53, 9 CFR 71]
Contagious Bovine Pleuropneumonia [9 CFR 71]
Contagious Equine Metritis [9 CFR 71]
Dourine [9 CFR 71]

Exotic Newcastle Disease [9 CFR 53, 9 CFR 82]
Foot-and-Mouth disease [9 CFR 53, 9 CFR 71]
Glanders [9 CFR 71]
Highly Pathogenic Avian Influenza (European Fowl Pest) [9 CFR 53, 9 CFR 71]
Rinderpest [9 CFR 53]
Scabies – Sheep [9 CFR 53]
Teschen Disease [9 CFR 71]
Screwworm [9 CFR 71]
Swine Vesicular Disease [9 CFR 53]
Vesicular Exanthema [9 CFR 71]

Title 9 of the CFR provides regulations for accredited veterinarians, and for State and Federal veterinarians acting in an official animal health capacity. Accredited veterinarians must report immediately to the AVIC and the SAHO all diagnosed or suspected cases of a communicable disease for which APHIS has a control or eradication program for in 9 CFR Chapter I, and for all diagnosed or suspected cases of any animal disease not known to exist in the United States as provided by 9 CFR 71.3 (b). [9 CFR 161.3 (f)]

C. The Agricultural Bioterrorism Protection Act of 2002

The Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins, 7 CFR Part 331 and 9 CFR Part 121, provides that the United States prevent, prepare for, and respond to bioterrorism and other public health emergencies that could threaten public health and safety or American agriculture. The Act requires that individuals possessing, using, or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products to notify either the Secretary of the Department of Health and Human Services or the Secretary of the Department of Agriculture. The Act includes safeguards and restrictions for select biological agents, including specific FAD agents.

VII. INQUIRY

Any questions regarding these procedures or instructions should be directed to the NCAHEM Staff (Attachment I).

VIII. GLOSSARY OF ACRONYMS

Animal Health Protection Act (AHPA)

Animal and Plant Health Inspection Service (APHIS)

APHIS Legislative and Public Affairs Staff (LPA)

Area Veterinarian in Charge or Designee (AVIC)

VIII. GLOSSARY OF ACRONYMS, CONTINUED

Emerging Disease Incidents (EDI)

Emergency Management Response System (EMRS)

Foreign Animal Disease (FAD)

Foreign Animal Disease Diagnostician (FADD)

National Animal Health Laboratory Network (NAHLN)

- NAHLN Laboratory Director or Designee (NAHLN Director)

National Veterinary Services Laboratories (NVSL)

- NVSL Director or Designee (NVSL Director)

State Animal Health Official or Designee (SAHO)

United States Department of Agriculture (USDA)

Veterinary Services (VS)

VS Deputy Administrator (VS DA)

VS Associate Deputy Administrators (VS ADAs)

- VS Chief of Field Operations, Associate Deputy Administrator (ADA)
- VS Chief Policy Officer, Associate Deputy Administrator (ADA), National Animal Health Policy and Programs (NAHPP)
- VS Chief Science Officer, Associate Deputy Administrator (ADA), Emergency Management and Diagnostics (EM&D)

VS Emergency Management Leadership Team (EMLT)

VS National Center for Animal Health and Emergency Management (NCAHEM)

- NCAHEM Preparedness and Incident Coordination Staff (PIC)
- NCAHEM National Veterinary Stockpile Staff (NVS)

VS Region Director or Designee (Region Director)

IX. LIST OF ATTACHMENTS

Attachment I: USDA APHIS VS NCAHEM Contact Information

Attachment II: Field Guide to the Classification of FAD/EDI Investigations and Correlation to Designation of Diagnostic Sample Priority 1, 2, 3, or A (Summary of Section IV)

IX. LIST OF ATTACHMENTS, CONTINUED

Attachment III: Field Guide to the Submission of FAD/EDI Investigation Diagnostic Samples to NVSL-AMES, NVSL-FADDL, and NAHLN Laboratory

Attachment IV: NVSL FAD/EDI Contact Information and FedEx[®] Airbill Information

Attachment V: EMRS FAD/EDI Investigation Reporting Instructions

Attachment I

**USDA APHIS VS Emergency Management and Diagnostics (EM&D)
National Center for Animal Health Emergency Management (NCAHEM)**

**NCAHEM Main Office Number
301-734-8073**

**NCAHEM 24/7 Emergency Answering Service
Foreign Animal Disease Investigations or Emerging Disease Incidents
National Veterinary Stockpile Activation
Toll Free Number
1-800-940-6524**

NCAHEM

National Veterinary Stockpile Staff (NVS)
Preparedness and Incident Coordination Staff (PIC)
Interagency Coordination Staff (ICS)

Normal Business

Monday – Friday
8:00 a.m. to 5:00 p.m. Eastern Time

NVS, PIC, & ICS

Main Office Number: 301-734-8073
Main Fax Number: 301-734-7817

USDA APHIS VS EMD NCAHEM		
24/7 Emergency Answering Service Toll Free Number 1-800-940-6524		
Normal Business Monday–Friday 8:00 a.m. to 5:00 p.m. Eastern Time Main Office Numbers: NVS, PIC, & ICS 301-734-8073 (phone) 301-734-7817 (fax)		
PIC Staff Person	Desk	Mobile
Jon Zack	301-734-0827	240-252-8074
Randy Crom	301-734-8423	240-508-9753
Steve Finch	301-734-0823	240-508-8619
Diego Fridmann	301-734-7781	240-252-8089
Conrad Estrada	301-734-0487	240-508-8647

Attachment II

Field Guide to the Classification of FAD/EDI Investigations and Designation of Diagnostic Sample Priority 1, 2, 3, or A (Summary of Section IV)

- Table 1) Classification of FAD Investigations and Correlation to Designation of Diagnostic Sample Priority 1, 2, 3, or A**
- Table 2) Classification of FAD Investigations and Definitions**
- Table 3) Designation of Diagnostic Sample Priority 1, 2, 3, or A and Correlation to Speed of Sample Collection, Transportation, and Diagnostic Study**
- Table 4) Checklist for the Classification of FAD/EDI Investigations and Designation of Diagnostic Sample Priority 1, 2, 3, or A**

Table 1) Classification of FAD/EDI Investigations and Correlation to Designation of Diagnostic Sample Priority 1, 2, 3, or A	
Classification of Investigations	Designation of Diagnostic Sample Priority
High Suspicion of an FAD/EDI <i>Formerly “Highly Likely”</i>	Diagnostic Sample Priority 1
Intermediate Suspicion of an FAD/EDI <i>Formerly “Possible”</i>	Diagnostic Sample Priority 2 or Priority A
Low Suspicion of an FAD/EDI <i>Formerly “Unlikely”</i>	Diagnostic Sample Priority 3 or Priority A

Table 2) Classification of FAD/EDI Investigations and Definitions	
Classification of Investigations	Definition
High Suspicion of an FAD/EDI <i>Formerly “Highly Likely”</i>	The findings of the investigation conducted by the FADD are consistent with an FAD/EDI and are generally inconsistent with an endemic disease/condition, or are discordant with an endemic disease/condition. The veterinary medical and regulatory assessments are consistent with a <u>high suspicion of an FAD/EDI classification</u> (<i>formerly “Highly Likely” classification</i>).
Intermediate Suspicion of an FAD/EDI <i>Formerly “Possible”</i>	The findings of the investigation conducted by the FADD are consistent with an FAD/EDI but are also consistent with an endemic disease/condition. The veterinary medical and regulatory assessments are consistent with an <u>intermediate suspicion of an FAD/EDI classification</u> (<i>formerly “Possible” classification</i>).
Low Suspicion of an FAD/EDI <i>Formerly “Unlikely”</i>	The findings of the investigation conducted by the FADD are generally inconsistent with an FAD/EDI and are consistent with an endemic disease/condition. The veterinary medical and regulatory assessments are consistent with a <u>low suspicion of an FAD/EDI classification</u> (<i>formerly “Unlikely” classification</i>).

Table 3) Designation of Diagnostic Sample Priority 1, 2, 3, or A and Correlation to Speed of Sample Collection, Transportation, and Diagnostic Study	
Priority	Speed of Sample Collection, Transportation, and Diagnostic Study
Priority 1	<ul style="list-style-type: none"> ▪ The Priority 1 designation is ONLY used for the <u>High Suspicion of an FAD/EDI classification</u>. ▪ Rapid to extraordinary rapid methods must be used to collect, transport, and study diagnostic samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies as rapidly as possible upon sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by state. ▪ Extraordinary rapid collection and transportation methods will be required when the Priority 1 investigation includes a highly contagious FAD/EDI in the differential diagnosis; or when the Priority 1 investigation includes animals, animal products, meat, articles or conveyances involved or engaged in interstate or international commerce.¹ ▪ Rapid transportation methods include express shipping services such as FedEx® priority overnight. ▪ Extraordinary rapid transportation methods include the use of hand carried samples, couriers, counter-to-counter services, and complete commercial services such as Air Net, FedEx® Custom Critical, and UPS Express Critical.
Priority 2	<ul style="list-style-type: none"> ▪ The Priority 2 designation is used for the <u>Intermediate Suspicion of an FAD/EDI classification</u>. ▪ Rapid methods must be used to collect, transport, and study diagnostic samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies immediately if the samples arrive at the laboratory before the close of the work day. NVSL will use overtime to complete testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by state. Diagnostic samples arriving after the close of the work day will be examined first thing the following day. Diagnostic samples received Saturday will be tested or studied on Saturday only with prior notification and discussion with NVSL and NAHLN laboratory personnel. ▪ Rapid transportation methods include express shipping services such as FedEx® priority overnight.
<p>¹ Examples of animals, animal products, meat, articles, or conveyances in interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; interstate or international import-export facilities.</p>	
<p>Table 3 is continued on the next page.</p>	

Table 3: Designation of Diagnostic Sample Priority 1, 2, 3, or A and Correlation to Speed of Sample Collection, Transportation, and Diagnostic Study, Continued	
Priority	Speed of Sample Collection, Transportation, and Diagnostic Study
Priority 3	<ul style="list-style-type: none"> ▪ The Priority 3 designation is only used for the <u>Low Suspicion of an FAD/EDI classification</u>. ▪ Routine methods will be used to collect, transport, and study diagnostics samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies in accession order as received. NVSL and NAHLN overtime services will not be used for Priority 3 investigations. The Priority 3 designation is also used for routine surveillance samples. ▪ Routine transportation methods include express shipping services such as FedEx® priority overnight (to ensure preservation of diagnostic sample quality).
Priority A	<ul style="list-style-type: none"> ▪ The Priority A designation is ONLY used for <u>Intermediate Suspicion of an FAD/EDI classification</u> or <u>Low Suspicion of an FAD/EDI classification</u> when animals, animal products, meat, articles or conveyances in interstate, or international commerce are involved and/or potentially held, delayed or quarantined pending the results of diagnostic testing or studies for an FAD; or when other known or potential circumstances associated with the investigation indicate that it is prudent to obtain diagnostic sample testing results as rapidly as possible.¹ ▪ Rapid to extraordinary rapid measures must be employed to collect, transport, and study diagnostic samples. ▪ NVSL and NAHLN personnel will perform diagnostic testing and studies as rapidly as possible upon sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by state. ▪ Rapid transportation methods include express shipping services such as FedEx® priority overnight. ▪ Extraordinary rapid transportation methods include the use of hand carried samples, couriers, counter-to-counter services, and complete commercial services such as Air Net, FedEx® Custom Critical, and UPS Express Critical.
<p>¹ Examples of animals, animal products, meat, articles, or conveyances in interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; interstate or international import-export facilities.</p>	
<p>This is the continuation of Table 3</p>	

Table 4) Checklist for the Classification of FAD/EDI Investigations and Designation Of Diagnostic Sample Priority 1, 2, 3, or A. See Section IV-B for Complete Instructions.	
1	The FADD, AVIC, and SAHO must concur on the: a) Classification of investigation; and, b) Designation of diagnostic sample priority 1, 2, 3, or A.
2	The Priority 1 diagnostic sample designation is <u>ONLY</u> used for the <u>High Suspicion of an FAD/EDI classification</u> .
3	The Priority A diagnostic sample designation is <u>ONLY</u> used for: a) The <u>Intermediate Suspicion of an FAD/EDI classification</u> ; or, b) The <u>Low Suspicion of a FAD/EDI classification</u> ; c) When animals, animal products, meat, articles, or conveyances in interstate or international commerce are involved and/or potentially held, delayed or quarantined pending the results of diagnostic testing or studies for an FAD/EDI; or, d) When other known or potential circumstances associated with the investigation indicate that it is prudent to obtain diagnostic sample testing results as rapidly as possible, regardless of the likelihood of the presence of an FAD/EDI.
4	If there are questions, concerns or disagreement regarding the classification of an investigation or the designation of diagnostic sample Priority 1, 2, 3, or A by the FADD, AVIC, and the SAHO, then there must be an immediate conference call of the FADD, AVIC, and SAHO(s) with the Region Director or designee, NVSL Director, and NCAHEM PIC. NCAHEM PIC and Region Director or designee will provide the capability to host and coordinate conference calls.
5	IMMEDIATELY contact NCAHEM PIC and Region Director or designee by phone and prior to shipment or transport of diagnostic samples when: a) <u>High Suspicion of an FAD/EDI “Highly Likely” classification</u> is assigned; or, b) Priority 1 diagnostic sample designation is assigned; or, c) Priority A diagnostic sample designation is assigned; d) These diagnostic samples will require rapid to extraordinary rapid transportation methods to include hand carried samples, courier, counter-to-counter services, and complete commercial services such as FedEx® Custom Critical, AirNet, or UPS Express Critical.
6	The appropriate NVSL-AMES or NVSL-FADDL Laboratory must be contacted by phone prior to the shipment or transport of any diagnostic samples, regardless of the Priority 1, 2, 3, or A designation. If a second set of samples is going to be submitted to a NAHLN Laboratory, then the NAHLN Laboratory must be contacted by telephone prior to the shipment or transport of any diagnostic samples.
7	EMRS must be used for all FAD/EDI investigations. Automatic email notifications are generated for all FAD/EDI investigations. Telephone notifications to NCAHEM PIC are NOT required for the <u>Intermediate Suspicion of an FAD/EDI classification</u> , <u>Low Suspicion of an FAD/EDI classification</u> , or Priority 2 or Priority 3 diagnostic sample designations.

Table 4) Checklist for the Classification of FAD/EDI Investigations and Designation Of Diagnostic Sample Priority 1, 2, 3, or A. See Section IV-B for Complete Instructions, Continued.	
8	<p>Following initial telephone notifications of a <u>High Suspicion of an FAD/EDI classification</u>, or any Priority 1 or Priority A diagnostic sample designations, the FADD, AVIC, SAHO(s), Region Director(s) or designee(s), NVSL Director, NAHLN Laboratory Director, and NCAHEM PIC will immediately discuss by phone or conference calls (within 2 hours of NCAHEM PIC notification):</p> <ul style="list-style-type: none">a) The rapid to extraordinary rapid measures to be used to collect, transport, and test diagnostic samples;b) The veterinary medical countermeasures, regulatory actions, and communications to be recommended and implemented during the investigation period, as necessary, to prevent and/or mitigate the dissemination of a FAD/EDI agent by interstate or international commerce.c) NCAHEM PIC and Region Director or designee will provide the capability to host conference calls.

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Attachment III

Field Guide to the Submission of FAD/EDI Investigation Diagnostic Samples to NVSL-AMES, NVSL-FADDL, and NAHLN Laboratory

- Table 1) Checklist for the Submission of FAD/EDI Investigation Diagnostic Samples to NVSL-AMES and NVSL-FADDL Laboratories**
- Table 2) Checklist for the Submission of a Second Set of FAD/EDI Investigation Diagnostic Samples to a NAHLN Laboratory**
- Table 3) Table for Routing Diagnostic Sample Submissions to NVSL-AMES or NVSL-FADDL Laboratories**

Table 1) Checklist for the Submission of FAD/EDI Investigation Diagnostic Samples to NVSL-AMES or NVSL-FADDL Laboratories	
1	<p>The AVIC or FADD must IMMEDIATELY contact NCAHEM and the Region Director or designee by phone and prior to shipment or transport of diagnostic samples when:</p> <ul style="list-style-type: none"> a) <u>High Suspicion of an FAD/EDI “Highly Likely”</u> investigation classification is assigned; or, b) Priority 1 diagnostic sample designation is assigned; or, c) Priority A diagnostic sample designation is assigned; d) These diagnostic samples will require rapid to extraordinary rapid transportation methods that include courier, counter-to-counter services, or complete commercial services such as FedEx® Custom Critical, AirNet, or UPS Express Critical.
2	<p>Contact the appropriate NVSL-AMES or NVSL-FADDL Laboratory by phone prior to the shipment or transport of diagnostic samples, regardless of diagnostic sample Priority 1, 2, 3, or A designation. Information required:</p> <ul style="list-style-type: none"> a) Airbill tracking number, or other transport identification; b) Estimated time and day the diagnostic samples will arrive; c) Classification of investigation; d) Priority 1, 2, 3, or A diagnostic sample designation.
3	<ul style="list-style-type: none"> ✓ If calling after business hours, weekends or holidays, leave a complete message on the answering machine for NVSL-AMES or NVSL-FADDL, including name of shipper, origin, estimated time of arrival of the package, Airbill tracking number (or other transport identification), or airline name, and flight number. ✓ Leave name and a call-back phone number so the information can be verified.
4	<ul style="list-style-type: none"> ✓ If a courier, counter-to-counter service, or complete commercial service is used to transport diagnostic samples to NVSL-AMES or NVSL-FADDL, the carrier or transporter must notify the appropriate laboratory as soon as possible with the flight details, so that an NVSL representative can make arrangements to meet the courier, counter-to-counter service, or complete commercial carrier service. ✓ When samples are hand-carried or transported by complete commercial carrier service to NVSL-FADDL, the carrier or coordinator must notify FADDL well in advance, so that security personnel at Plum Island can be given proper notification, and arrangements made for a FADDL representative to meet the carrier or transporter at the security gate, Plum Island helicopter pad, airport, or other location.

Table 1) Checklist for the Submission of FAD/EDI Investigation Diagnostic Samples to NVSL-Ames or NVSL-FADDL Laboratories, Continued.	
5	<ul style="list-style-type: none"> ✓ The closest Airport to Plum Island (NVSL-FADDL) is approximately 60 miles west at the Long Island/MacArthur Airport. JFK International or LaGuardia Airports are approximately 110 miles west from Plum Island.
6	<ul style="list-style-type: none"> ✓ The FedEx® Airbill tracking number or other transport identification must be used to track the diagnostic samples from the field to the laboratory. ✓ The airbill tracking number must be listed on the EMRS FAD/EDI Investigation Summary Form and <u>VS Form 10-4 Specimen Submission Form</u>.
7	<ul style="list-style-type: none"> ✓ The packaging and labeling of biological substances for shipment requires familiarity and training with current rules and regulations, which frequently change. Shippers are responsible for proper packaging, marking and labeling, documentation, classification, and identification of each shipment. Failure to follow regulations can result in substantial financial penalties. ✓ Airline shipments also should be in compliance with current International Air Transport Association (IATA) regulations (www.iata.org) for dangerous goods. ✓ Additional information is available at the following website: http://www.aphis.usda.gov/animal_health/lab_info_services/packaging_labeling.shtml
8	<ul style="list-style-type: none"> ✓ A completed and legible <u>VS Form 10-4 Specimen Submission Form</u> must accompany all diagnostic samples in each box of diagnostic samples sent to NVSL-Ames and NVSL-FADDL. ✓ Attach a <u>VS Form 10-4A Specimen Submission Form Continuation Sheet</u> if needed to account for all specimens included in the shipment or to fully describe all findings and other relevant information.
9	<p>The completed <u>VS Form 10-4 Specimen Submission Form</u> must contain as much of the information listed below that is known, for custody and control purposes, and to assist the laboratory diagnostician:</p> <ul style="list-style-type: none"> a) EMRS Referral Control Number; b) Airbill tracking number (or other transport identification); c) City, County, State of premises under investigation; d) Name of the producer, owner, manager or agent; e) Species, breed, or type, and number of animals on premises; f) Additional Data: history, clinical signs, necropsy findings, presumptive field diagnosis with differential diagnoses; g) When diagnostic samples are submitted for multiple animals, for each animal record the animal's identification, lesions, clinical signs, etc., and if necropsy was performed record the gross pathology findings; the animal's identification will be linked to the diagnostic study for the animal; h) Classification of investigation; i) Priority 1, 2, 3, or A diagnostic sample designation.
10	<ul style="list-style-type: none"> ✓ The completed <u>VS Form 10-4 Specimen Submission Form</u> must be placed on top of the styrofoam box or styrofoam lid (inside the cardboard box) but not inside the styrofoam container with the diagnostic samples.

2) Checklist for the Submission of a Second Set of FAD/EDI Investigation Diagnostic Samples to a NAHLN Laboratory	
1	<ul style="list-style-type: none"> ✓ There are several capabilities and options available for FAD/EDI diagnostic testing depending upon the classification of FAD/EDI investigation and designation of diagnostic sample priority. ✓ For some FAD/EDI investigations, the extraordinary rapid transportation of diagnostic samples to NVSL-AMES or NVSL-FADDL by complete commercial carrier service will be the best option (such as Air Net, FedEx® Custom Critical, and UPS Express Critical). ✓ For some FAD/EDI investigations, obtaining two sets of diagnostic samples will be the best option. The first set of diagnostic samples must always be sent to the appropriate NVSL Laboratory (NVSL-AMES or NVSL-FADDL). The second set of diagnostic samples (if possible) will be sent to a NAHLN Laboratory to provide preliminary diagnostic information prior to the receipt of diagnostic samples by the NVSL Laboratory. ✓ For some FAD/EDI investigations, the rapid transportation of one set of diagnostic samples to NVSL-AMES or NVSL-FADDL will be the best option (such as FedEx® priority overnight).
2	<ul style="list-style-type: none"> ✓ The AVIC and SAHO will determine a diagnostic sample submission plan with the FADD, NVSL, and the NAHLN Laboratory Director. ✓ If the preliminary decision is made to submit a second set of diagnostic samples to the NAHLN laboratory, then the AVIC and/or SAHO must instruct the FADD to follow the procedures for submitting a second set of diagnostic samples to the NAHLN laboratory. ✓ The AVIC, SAHO or FADD will notify the NAHLN Laboratory Director if there is a change in the NAHLN laboratory submission plan after the FADD performs the investigation.
3	<ul style="list-style-type: none"> ✓ The FADD, AVIC, and SAHO must concur with the classification of investigation and designation of diagnostic sample Priority 1, 2, 3 or A.
4	<ul style="list-style-type: none"> ✓ If a second set of diagnostic samples can not be collected, then the samples that can be collected must be sent to the appropriate NVSL Laboratory, and not to the NAHLN Laboratory.
5	<ul style="list-style-type: none"> ✓ The appropriate NVSL-AMES or NVSL-FADDL Laboratory must be contacted by phone prior to the shipment or transport of any diagnostic samples, regardless of the Priority 1, 2, 3, or A designation. If a second set of samples is going to be submitted to a NAHLN laboratory, then the NAHLN laboratory must be contacted by telephone prior to the shipment or transport of any diagnostic samples.

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3) Table for Routing Diagnostic Sample Submissions to NVSL-AMES and NVSL-FADDL Laboratories		
Type of Diagnostic Specimen:	NVSL AMES	NVSL FADDL
Ruminants <ul style="list-style-type: none"> ▪ Bovine spongiform encephalopathy (BSE) suspects ▪ Heartwater suspects ▪ Bovine babesiosis ▪ All other ruminant specimens 	PL DVL DBL No	No No No FADDL
Avian	DVL	No
Entomologic specimens, all species	PL	No
Equine <ul style="list-style-type: none"> ▪ African horse fever (AHF) ▪ Dourine & Glanders ▪ Contagious equine metritis (CEM) ▪ Equine piroplasmosis 	DVL DBL DBL DBL	No No No No
Swine <ul style="list-style-type: none"> ▪ Foot-and-mouth disease (FMD) suspects ▪ Swine vesicular disease (SVD) suspects ▪ Classical swine fever (CSF) suspects ▪ African swine fever (ASF) suspects ▪ All other swine diagnostic samples ✓ See notes and instructions below for swine sample submissions 	No No No No DVL -	FADDL FADDL FADDL FADDL No -
Notes and Instructions		
NVSL-Ames Laboratories: DVL = Diagnostic Virology Laboratory PL = Pathobiology Laboratory DBL = Diagnostic Bacteriology Laboratory	NVSL FADDL = Foreign Animal Disease Diagnostic Laboratory	
<p>Swine sample submission notes and instructions:</p> <ul style="list-style-type: none"> ✓ NVSL strongly recommends that if CSF or ASF is suspected and non-FAD conditions are included in the differential diagnosis, then one set of diagnostic samples be sent to NVSL-FADDL and a second set of diagnostic samples be sent to NVSL-AMES-DVL. ✓ The diagnostic samples submitted to NVSL-AMES-DVL must be clearly marked “Hold until cleared for exotic disease by FADDL.” ✓ Notify NVSL-FADDL and NVSL-AMES when two or more sets of samples are being shipped or transported for the same investigation. 		
<p>General note and instruction:</p> <ul style="list-style-type: none"> ✓ If more than one laboratory at NVSL-AMES is requested to perform diagnostic testing (i.e., DVL, PL, DBL) then the separate sets of diagnostic samples need to be labeled for each NVSL-AMES Laboratory. 		

Attachment IV

NVSL FAD/EDI Contact Information and FedEx® Airbill Information

A. NVSL-AMES Contact Information and FedEx® Airbill Information

1) NVSL-AMES Must be Contacted by Phone Prior to Shipment or Transport of Diagnostic Samples Regardless of Priority 1, 2, 3, or A Diagnostic Sample Designation.

2) NVSL-AMES Phone Contact Information During Business Hours:

Monday-Friday 8:00 am – 4:30 pm Central Time

<u>Department Laboratory</u>	<u>Phone Number</u>
Diagnostic Virology	(515) 663-7551
Diagnostic Pathobiology	(515) 663-7521
Diagnostic Bacteriology	(515) 663-7563

After Hours and Weekends 24/7

National Animal Disease Center Dispatch: (515) 663-7200

If you leave a voice message, include your name and a call-back number.

3) Priority 1 or Priority A Diagnostic Samples Transported by Courier, Counter-to-Counter Service, or Complete Commercial Carrier such as FedEx® Custom Critical, AirNet or UPS Express Critical:

- a) Call NCAHEM PIC and Region Director or designee immediately to arrange transportation details.
- b) Call NVSL-AMES immediately to arrange diagnostic sample and transportation details.

4) Priority 1, 2, 3, or A Diagnostic Samples Shipped by FedEx® Priority Overnight:

Phone contact or notification must be made with NVSL-Ames prior to shipment of Priority 1, 2, 3, or A diagnostic samples by FedEx® Priority Overnight.

NVSL-AMES Address for the FedEx® Airbill:

**USDA, NVSL
1800 Dayton Road
Ames, Iowa 50010**

FedEx® Priority Overnight Airbill Instructions:

- a. Billing/Payment: use the billing number or account number obtained from the AVIC.
- b. Internal Billing Reference (Section 2), use the accounting code obtained from the AVIC.
- c. Check the FedEx® Priority Overnight box (Section 4a).
- d. Saturday delivery should be marked for Priority 1, 2, 3, and A samples sent on Friday.
- e. Retain the sender's copy of the airbill for your records.

B. NVSL-FADDL Contact Information and FedEx® Airbill Information

1. NVSL- FADDL MUST be Contacted by Phone Prior to Shipment or Transport of Diagnostic Samples Regardless of Priority 1, 2, 3, or A Diagnostic Sample Designation.

Arrangements must always be made to pick up the diagnostic samples from the Federal Express office, or meet a courier, or meet counter-to-counter service at an airport or other location. Unless FADDL is notified by phone prior to the shipment or transport, the diagnostic samples will be delayed in delivery to FADDL.

2. NVSL-FADDL Contact Information:

During Business Hours

Monday-Friday
8:30 am – 4:15 pm Eastern Time

Main Office Number

(631) 323-3256 or (631) 323-3206

After Hours and Weekends

Samia Metwally
Acting Diagnostic Services Section Head
Barry Latney

Phone Number

(631) 375-5314
(631) 332-6814
(631) 871-3112

After Hours and Weekends: If Unable to Reach Someone Listed Above

National Animal Disease Center Dispatch: (515) 663-7200

If you leave a voice message, include your name and a call-back phone number.

3. Priority 1 or Priority A Diagnostic Samples Transported by Courier, Counter-to-Counter, FedEx® Custom Critical, AirNet or UPS Express Critical:

- a) Call NCAHEM PIC and Region Director or designee immediately to arrange transportation details.
- b) Call NVSL-FADDL immediately to arrange diagnostic sample collection and transportation details.

4. Priority 1, 2, 3, or A Diagnostic Samples Shipped by Federal Express Priority Overnight: FedEx® Airbill Instructions:

Phone contact or notification must be made with NVSL- FADDL prior to shipment of Priority 1, 2, 3, or A samples by FedEx® Priority Overnight.

USDA/APHIS/FADDL

**Orient Point Warehouse, 40550 Rte 25
579 Edwards Ave., Calverton, NY 11933
Orient Point
NY
11957**

“Company” (Section 3):

“Recipient’s Address” (Section 3):

“Address” (Section 3):

“City” (Section 3) :

“State” (Section 3)

“Zip” (Section 3)

FedEx® Airbill Section 3: “Address”

Shipper must include the FedEx® Calverton Office address: 579 Edwards Ave., Calverton, NY 11933. The additional FedEx® Calverton Office address (and zip code) enables NVSL-FADDL personnel to pick up the package as soon as possible in the morning, therefore

Veterinary Services Memorandum 580.4 – Attachment IV

allowing a full day of laboratory testing and studies. A sample FedEx® Airbill for NVSL-FADDL is included below.

FedEx® Airbill Section 6: “Special Handling”

Check Box “HOLD Weekday at FedEx Location” – If received Monday-Friday
 Check Box “HOLD Saturday at FedEx Location” – If received Saturday

Priority 1, 2, 3, or A diagnostic samples sent on Friday for Saturday delivery will be held at the FedEx® office until Monday unless prior arrangements for Saturday diagnostic testing are made with FADDL personnel. Note that the box “HOLD Saturday at FedEx® Location” must be checked for samples received on Saturday (FedEx® Airbill Section 6, “Special Handling”).

Other Federal Express Priority Overnight Airbill Instructions

- a. Billing/Payment: use the billing number or account number obtained from the AVIC.
- b. Internal Billing Reference (Section 2): use the accounting code obtained from the AVIC.
- b. Check the FedEx® Priority Overnight box (Section 4a).
- c. Saturday delivery must be marked for Priority 1, 2, 3, and A samples sent on Friday.
- d. Retain the sender’s copy of the airbill for your records.

5. Sample FedEx® Airbill for NVSL-FADDL (for Weekday delivery).

FedEx. US Airbill FedEx Tracking Number: 1234 5678 901C

1 From Please print and print bold Sender's FedEx Account Number: NUMBER ONLY
 Date: _____
 Sender's Name: _____ Phone: _____
 Company: _____
 Address: _____ Dept./Floor/Suite/Room: _____
 City: _____ State: _____ ZIP: _____

2 Your Internal Billing Reference First 30 characters will appear on invoice. OPTIONAL

3 To Recipient's Name: **USDA/APHIS/FADDL**
 Company: _____
 Recipient's Address: **Orient Point Warehouse, 40550 Rte 25**
 We cannot deliver to P.O. boxes or P.O. ZIP codes. Dept./Floor/Suite/Room: _____
 Address: **579 Edwards Ave., Calverton, NY 11933**
 To request a package be held at a specific FedEx location, print FedEx address here.
 City: **Orient Point** State: **NY** ZIP: **11957**

4a Express Package Service Packages up to 150 lbs.
 FedEx Priority Overnight Next business morning. **Friday shipments will be delivered on Monday unless SAT/USPS Delivery is selected.
 FedEx Standard Overnight Next business afternoon. Saturday Delivery NOT available.
 FedEx 2Day Second business day. **Thursday shipments will be delivered on Monday unless SAT/USPS Delivery is selected.
 FedEx Express Saver Third business day. Saturday Delivery NOT available.
 FedEx locations may not be available. Minimum charge. One parcel only. *To most locations. **To some locations.

4b Express Freight Service Packages over 150 lbs.
 FedEx 1Day Freight® Next business day. **Friday shipments will be delivered on Monday unless SAT/USPS Delivery is selected.
 FedEx 2Day Freight Second business day. **Thursday shipments will be delivered on Monday unless SAT/USPS Delivery is selected.
 **To most locations.

5 Packaging
 FedEx Envelope® FedEx Pak® Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak. FedEx Box FedEx Tube Other *Declared value limit \$500.

6 Special Handling (Circle FedEx address in Section 3)
 SATURDAY Delivery **To most locations.
 HOLD Weekday at FedEx Location Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations.
 HOLD Saturday at FedEx Location Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations.
 Does this shipment contain dangerous goods?
 No Yes Do not ship dangerous goods in FedEx packaging. Yes Do not ship dangerous goods in FedEx packaging. Dry Ice Dry Ice, N, UN 1845 Cargo Aircraft Only
 Dangerous goods (including dry ice) cannot be shipped in FedEx packaging.

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Total Packages: 1 Total Weight: 1 Total Declared Value*: \$ 450.00
 *Your liability is limited to \$500 unless you declare a higher value. See back for details. By accepting this bill you agree to the service conditions on the back of this bill and to the current FedEx Service Guide, including terms that limit our liability.

8 Residential Delivery Signature Options If you require a signature, check Direct or Indirect.
 No Signature Signature required. Package may be left without a signature for delivery. Direct Signature Recipient or consignee's address may sign for delivery. Fee applies. Indirect Signature The mail is available at recipient's address, someone at a neighboring address may sign for delivery. Fee applies. **520**

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Attachment V

Emergency Management Response System (EMRS) FAD/EDI Investigation Reporting Instructions

1. Introduction

- The EMRS “Routine FAD/EDI Reporting” is a web enabled database that is the official USDA APHIS database to record all FAD/EDI investigations.
- The EMRS database provides the capability to generate automatic email notices to selected VS personnel when FAD/EDI investigations are initiated in EMRS. This capability enables VS Region and NCAHEM to monitor potential national “clusters” of FAD/EDI investigations on a real-time basis.
- The EMRS database is accessed through the internet (<http://emrs.aphis.usda.gov>) and permits approved State and VS personnel access to enter and view investigations from their State or territory. All entries are confidential. EMRS database access at the State or territory is controlled and maintained by approval of the AVIC and the State Animal Health Official.
- The AVIC and/or State Animal Health Official will designate an FAD/EDI EMRS Case Coordinator to perform or facilitate EMRS data entry and database maintenance, as necessary.
- An EMRS Manual for Routine FAD/EDI Investigations can be downloaded, as well as blank investigation forms. There is a training investigation module for practice investigations and an online tutorial.

2. Referral Control Number (RCN)

- The AVIC will ensure that an 8-character referral control number (RCN) is assigned for each FAD/EDI investigation, and transmitted to the FADD and State Animal Health Official. The RCN must be entered on the Investigation Summary form and is assigned as in the following example:
 - 08CA0005
 - First 2 digits represent the Federal fiscal year (e.g., 08) in which the investigation will take place.
 - Next 2 characters represent the State or territory (e.g., California = CA) in which the primary premises investigated is located.
 - Next 4 digits specify the investigation number (e.g., 0005) for the fiscal year.
 - In this example, “08CA0005” represents the fifth FAD/EDI investigation conducted in the State of California during Federal fiscal year 2008.

3. Initiating an Investigation in EMRS

- The AVIC will assign an EMRS case coordinator, as necessary.
- First, the AVIC or case coordinator will determine if a Premises ID (Prem ID) already exists in the Generic Data Base (GDB). If no Premises ID exists, the

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AVIC or Case Coordinator will create a new Investigation Summary by creating a Premises ID (Prem ID) using the “NAIS Premises Allocator” on the FAD/EDI Investigation Database Main Menu. This allocator allows for “Address to Prem ID” and “Prem ID to Address” functions.

- If there is any difficulty in creating the Premises ID, then put the Referral Control Number (RCN) in both the Prem ID and RCN location. The Prem ID can be created at another time.
- The Investigation Summary is created by entering the Prem ID number, the Referral Control Number, animal location data, and premises owner/manager address data.
- After saving the Investigation Summary, the case coordinator information can be assigned (the AVIC or assigned case coordinator will be the case coordinator).
- A Herd Exam Follow-up form is initiated and the investigation is assigned to an FADD. Information obtained from the initial telephone call is entered in the Herd Exam form.

4. Premises Identification (Prem ID)

- A Premises ID (Prem ID) can be created using the “NAIS Premises Allocator” on the FAD/EDI Investigation Database Main Menu. This allocator allows for “Address to Prem ID” and “Prem ID to Address” functions.
- If there are any problems with “NAIS Premises Allocator” use the Referral Control Number as a temporary Premises ID and the EMRS team will assist to obtain a Premises ID after the FAD/EDI Investigation has begun.

5. Data Entry

- Once the FADD has completed the investigation, the findings should be entered into the database as soon as possible, with attention given to the Herd Exam Form, Lab Submission Form, and all applicable Follow-Up forms .

6. Notification of Investigation

- Automatic email notifications are generated for all FAD/EDI investigations. The FAD/EDI mailing group (NVSL-Ames, NVSL-FADDL, VS Region, and EM&D) will be notified when the FAD/EDI Investigation Summary is initiated in EMRS.
- Telephone notification to NCAHEM is not required for Intermediate Suspicion of an FAD/EDI “Possible” classification, Low Suspicion of an FAD/EDI “Unlikely” classification, or the Priority 2 or Priority 3 diagnostic sample designations.
- IMMEDIATELY contact NCAHEM and VS Region by phone and prior to shipment or transport of diagnostic samples when:
 - High Suspicion of an FAD/EDI “Highly Likely” investigation classification is assigned;
 - Or Priority 1 diagnostic sample designation is assigned;
 - Or Priority A diagnostic sample designation is assigned.

7. Follow-Up Forms

- This feature allows for the accurate chronology of the investigation. These forms are used to input additional information and the re-examination of animals.
- The AVIC must ensure the Lab Submission Form is completed when closing the investigation (if diagnostic samples were taken as part of the investigation).

8. Current Status and Status Form

- This feature allows the entry of quarantine and epidemiology zone information. The AVIC or Case Coordinator must ensure the Disease Control Closing Summary is completed when closing the investigation.

9. Maintenance and Review

- The AVIC must ensure FAD/EDI investigations for their Areas are maintained and reviewed in EMRS. This includes reviewing investigation reports to ensure all pertinent information is recorded and validated, cases are closed promptly, and to ensure that Lab Submission Form test results are completed when laboratory results are received (if diagnostic samples were taken as part of the investigation).